In Re:

Digitek

Daniel W. Bitler

January 22, 2010

Confidential – Subject to Further Confidentiality Review

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EXHIBIT C-1

UNITED STATES DISTRICT COURT

FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

- - -

IN RE: DIGITEK PRODUCTS LIABILITY LITIGATION : MDL NO. 1968

(This document relates to all cases.)

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CONFIDENTIAL - SUBJECT TO FURTHER CONFIDENTIALITY REVIEW

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Fairfield, New Jersey
Friday, January 22, 2010

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Videotaped Deposition of DANIEL W. BITLER held at Crowne Plaza, 690 Highway 46, on the above date, beginning at 9:09 a.m., before Kimberly A. Overwise, a Certified Realtime Reporter and Notary Public.

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A No. It was a formalized annualized session.

Q And did it take 20 minutes? Did it take an hour? Did it take two hours? Did it take all day?

A I believe it was approximately an hour.

Q Would you characterize it as a refresher course or was there an attempt to teach you new things?

A The annual program was more of a refresher course.

Q Do good manufacturing practices apply to Digitek?

A Yes.

Q And you understand that good manufacturing practices are set forth in federal regulations?

A Yes.

Q Do you understand that good manufacturing practices are minimum standards?

MR. MORIARTY: Objection.

BY MR. PETTIT:

Q Can you answer that?

A Good manufacturing practices are the requirement as put forth in the CFR.

Q Can a company exceed them and do a better job than the minimum standards set forth in the federal regulations?

MR. MORIARTY: Objection.

THE WITNESS: Companies can do what they need to do for their given operation or organization.

BY MR. PETTIT:

Q So they can't dip below the federal regulations for good manufacturing practices, but they can meet them or do better; correct?

MR. MORIARTY: Objection.

THE WITNESS: I would say yes.

BY MR. PETTIT:

Q Is it your understanding that failure to comply with good manufacturing products -- excuse me.

Is it your understanding that failure to comply with good manufacturing practices would render a product being, quote, adulterated, unquote?

A No.

subject a person or a company to regulatory action?

A Could you say the question again, please?

Q Sure. Is it your understanding that failure to comply with good manufacturing practices as set forth in the federal regulations could subject a company or person to regulatory action?

A Could? Yes.

(Plaintiff's Exhibit No. 127 was marked for identification.)

MR. MORIARTY: Jim, could either you or you, Ms. court reporter, just tell me what these exhibits are so I don't have to reach over and grab his?

MR. PETTIT: Sure. The LinkedIn resume was 126. And the current document which on the top says Actavis Totowa LLC standard operating procedure 06696, five pages, is Exhibit 127.

BY MR. PETTIT:

Q So that's the first page of a five-page document. And have you seen -- and

Q Yes, sir.
A SOP means standard operating procedure.
Q What does that mean?
A It's a description of procedures that are followed as part of the normal operations.
Q Does Actavis -- strike that.
Did Actavis create its own standard operating procedures for quality unit responsibilities?
A Yes.
Q And were you involved in drafting it or in commenting on it as it was being drafted?
A Yes.
Q Did you draft it?
A I approved it.
Q Who drafted it?
A I -- it says Bernard Glover so I would have to say Bernie, Prepared by.
Q Does it apply to Digitek?
A Yes.
Q I'm not going to spend a lot of time

Q What does out of specification mean as used in that sentence?
A Out of specification would be a laboratory testing result that did not meet acceptance criteria.
Q Is the acceptance criteria a document that is in writing?
A Yes.
Q Is the document that is in writing, does that apply to Digitek?
A There would be one for Digitek, yes.
Q Is there a separate one for Digitek?
A Yes.
Q What is that document called?
A This is a laboratory document. I don't know what the exact title of that would have been.
Q Can you remember a word or a phrase or what you might even informally call it?
A There were testing specifications. I don't remember what the title was that the lab had for their different documents.
Q And suspect test result, STR, what does that mean?

A Suspect test results, I believe -- again, I'm not a laboratory expert -- was results that were not out of spec but appeared to be varying from what had been seen in previous testing.

Q Is there a written document at Actavis that would distinguish an out of spec, OOS, from a suspect test result, STR?

A Yes, I believe there was.

Q What is that?

A Again, it's another procedural document from the laboratory. I don't know the title.

Q And in your career at Actavis, I'm assuming you did a lot of investigations of OOS?

A I did not conduct investigations of OOS.

Q Who did that?

A The laboratory.

Q And the same with suspect test results?

A That's correct.

Q And at a point -- and we're going to

inspection?

A Could you repeat the question again?

Q Sure. Were you involved in any corrective action plan that Actavis developed, which would be directed at correcting something that was observed in the 483 which arose out of the January-February 2006 inspection?

MR. MORIARTY: Objection.

Go ahead.

THE WITNESS: Can you define what you mean by "involved"? I'm not sure what you're trying to ask.

BY MR. PETTIT:

Q I'm trying to find out if you had any involvement so I can ask you more questions about it.

A Yes, I would have had some involvement.

Q What was that? Was that just talking to people about coming up with corrective actions, was that sitting and drafting documents, or something else?

A It could have been either one.

A Again, I would need to see that specific. I'm not sure if I was for that or not.

MR. PETTIT: All right. Can we take a break now?

MR. MORIARTY: Sure.

THE VIDEOGRAPHER: We are now going off the record. This is the end of Videotape No. 1. The time is 10:25.

(Short recess.)

THE VIDEOGRAPHER: We are now back on the record. This is the beginning of Videotape No. 2. The time is 10:35.

BY MR. PETTIT:

Q Mr. Bitler, I want to ask you some similar questions on another inspection. Are you familiar, just in general terms, are you familiar with an FDA inspection at Little Falls in September 2007?

A Yes.

Q Did you attend that, again, meaning, did you formally accompany and speak with the FDA people?

A No.
Q Did you read any of the documents authored by the FDA regarding the September 2007 inspection?
A The 483.
Q Did you contribute any documents to people at Actavis to assist in serving a formal response to the FDA?
A I was asked for input, yes.
Q Did you do it? Did you give documents?
A I provided some draft information, yes.
Q So drafting parts of the response or providing actual physical photocopies or both?
A Both.
Q And for the September 2007 inspection, to whom did you give the drafts and the documents?
A The response was being compiled by -- Scott Talbot and Phyllis Lambridis were in charge of compiling and formalizing the response.
Q Were you involved in drafting any

corrective action plans or providing any documents to help somebody else create a corrective action plan?

A Yes.

Q Which, drafting or documents, or both?

A 2007. I believe that would have been just providing documentation.

Q Are you generally familiar with there being an FDA inspection in March, April, and May of 2008?

A Yes.

Q Did you attend that inspection?

A I was introduced.

Q Did you formally walk around and formally answer any questions that the FDA people had?

A No, sir.

Q Did you read any of the documents authored by the FDA arising from that inspection?

A No, sir.

Q Did you draft any language for someone else to use in developing a formal

A Yes.

Q So my question then is: Are these 67 pages the sum total of Daniel Bitler's investigation report 07-093?

A This would be the final version of the investigation report.

Q And is it the complete version of the final investigation report 07-093?

A Without any other potentially referenced information, yes.

Q I have to ask you what that meant.

A I don't recall what's in all the text or in all the lab documents or in all the batch records that are copied here. There may be other things that are referenced in this document. I don't recall. But from this investigation report, this is the copy of the final report.

Q Is there a policy at Actavis -- was there a policy at Actavis in the end of 2007, beginning of 2008 on how to write an investigation report when there's a situation like this where out-of-spec tablets are found?

A We had a standard operating

procedure for how to conduct investigations.
Q And I think I saw the number for that in some document, but do you remember off the top of your head?
A No, sir. I'm sorry.
Q But it's a specific SOP for doing this kind of investigation report; correct?
A For --
MR. MORIARTY: Objection.
Go ahead.
THE WITNESS: For conducting an investigation.
BY MR. PETTIT:
Q And at the end of this kind of an investigation, you have to do an investigation report; correct?
A That's true, yes.
Q And if a vice president at Actavis said, Dan, where is your complete investigation report 07-093, would you say here it is, these 67 pages, or would you say you've got to look at a lot of other things?
A This would be the final report.
Q Do you have a recollection of this

document then. Going back to P-16 on Page 4: "Following the 100% inspection, the QA team conducted a 'Tightened' AQL inspection to ensure that the defect tablets have been removed from the batch. The tightened AQL inspection would require a rejection of the batch if as few as 2 tablets were found to have double tablet thickness."

So in Actavis, in a situation like this when you're looking at out-of-spec tablets, is there a policy that describes what decisions you should make, what procedures you should follow to decide whether you should reject or accept the batch if you find an additional one or two or three tablets?

MR. MORIARTY: Objection.

Go ahead.

THE WITNESS: Again, I'm sorry. I'm a little bit not certain as to the question. There is no procedure that encompasses all potential scenarios that you will encounter during the investigation process. There is a procedure for conducting investigations.

And based off that data and that evaluation, you come to a conclusion. But there is no procedure that says necessarily if this, then this, if this, then this, and go down the line through all the possible permutations that you might uncover. So I'm -- there isn't something that specifically says in the way of an Actavis policy that I'm aware of -- I can't speak now. We're talking about then.

BY MR. PETTIT:

Q We're only talking about then.

THE WITNESS: -- that would discuss AQL or how to handle AQL.

BY MR. PETTIT:

Q Do you know who drafted the sentence I just read: "The tightened AQL inspection would require a rejection of the batch if as few as 2 tablets were found to have double tablet thickness"?

A Again, as we said earlier, this portion of the investigation was drafted by Mike Ponzo. Now, again, there may have been

involvement in discussion of what was worded, but this was drafted by Mike.

Q Did Mike and you discuss whether there was a requirement to reject the batch if two tablets, two additional tablets were found to have double the thickness?

A Well, I believe that was based off the protocol.

Q Did you have a discussion with Mike? -- is my question.

A I don't recall if we did or not. This information here is being taken from the requirements of the protocol, I believe.

Q Tell me as precisely as you can where that requirement is drawn from.

A That requirement was drawn from military standard 105.

Q Anywhere else?

A No. Well, that's where the -- let me -- that's where the information that we used comes from, military standard 105. The document, if you will, it's more in the form of a type of a slide rule, is a sampling and inspection instrument that was put together by

ASQ.

Q Which is what?

A American Society of Quality. And Scott Talbot had one of these ASQ slide rules. It's hard to -- that's the best term I can give you. It's not really a slide rule. It's two documents, two pieces inside each other, and there's windows. And you move the slide depending upon various pieces of the puzzle that you have to answer. And it comes up with for a given inspection level what your accept and reject requirements would be.

Q What is it physically that you're describing? Is it a book?

A No. Like I said, it's more of a slide rule. You have a sleeve which has some windows cut out.

Q Oh, I getcha.

A And there's another piece inside. And you're able to slide that through the process depending upon which numbers you want to choose that match your situation. And as you work through that process, it provides you with the accept/reject criteria. But I can

tell you that that tool is based on military standard 105.

Q Does that ASQ -- I apologize. I scribbled. ASQ stands for?

A American Society of Quality.

Q Does the ASQ tool specifically as you slide these windows around say one tablet or two tablets or three tablets should be released --

A Yes, it does.

Q -- if there's a combination of sliding?

A Yes. It gives you an accept on blank, reject on blank. And that's based off whether it's tightened, whether it's normal, whether it's reduced. It's based off batch sizes. So there's a variety of things you use to come to that determination.

Q Going back to that decision whether the AQL inspection should be reduced, normal, or tightened, is there something in writing that you use to make that decision?

A There was not. Again, I don't know if there is now, but there was not. We chose

the tightest inspection criteria available on that tool.

Q Now, we're going to get to some pages that talk about 1,330 pills being tested and 40 in a bucket. So we're going to get to that and ask specific questions and get answers. But for those sorts of things -- and if you want to wait, we'll wait. But just generally for those sorts of decisions, is there a policy for those decisions that while you're doing the AQL inspection, you would pick a certain number of total tablets to do in the tightened AQL inspection?

A That number is given to you again from that tool. It tells you sample size as well.

Q Staying with P-16 and now turning if you'd be so kind to Page 6 of 67, I will zoom out for the big picture. And I'll go into what I want to ask about.

Those are your two signatures on that page; correct?

A Those are my signatures, that's correct.

A It would have come from discussions with regulatory affairs.

Q Who did you speak with?

A I do not recall which individual it might have been.

Q Did you speak with someone from regulatory affairs at Actavis about this issue?

A I believe so.

Q Would you have documented that conversation if there were that conversation?

A Not necessarily. I don't recall if I had.

Q Would there normally be a specific person at regulatory affairs that you would ask this question or have this discussion with even if you can't remember this specific discussion who it was?

A It changed over time.

Q How about in 2007; who likely if you had such a conversation would it be with?

A I can't remember the names. I'm drawing a blank. They were in Riverview and I can't recall their names.

tool or document other than the AQS to come up with that 1,250?

A The 1,250, right.

Q Or using the rounded up numbers of 40?

MR. MORIARTY: Objection. Are you talking about what they used or what's available?

MR. PETTIT: Well, I've been asking what's available at Actavis.

THE WITNESS: At Actavis, yes. I mean, but you have to remember the ASQ tool is simply a compilation of the information contained in military standard 105. So military standard 105 would be available in its entirety if you wanted to use that. This tool takes all the information and compiles it into one more usable format.

BY MR. PETTIT:

Q If I had the mil standard 105E I think it's called -- right?

A There's D or E, yeah. It depends which version.

Q That's not a section in your opinion? Is that a -- never mind.

If I had mil standard 105 and I had the AQS sliding window document, is that the entirety of what was available to you in end of 2007, beginning of 2008 to get the procedures for AQL inspection?

A Yes.

MR. MORIARTY: Next major convenient stopping point, we probably ought to go down there.

MR. PETTIT: I will do that.

BY MR. PETTIT:

Q Can you look at Page 61?

A Okay.

Q It's really hard to read on the screen. That is the numerical -- well, tell me what that is. I'm going to just zoom in.

A Yeah, you can't read the headers, but what it is in the document is simply a table that was used to capture the results of the AQL sampling that was done by quality assurance.

Q Okay. Now, tell me, if you would,

A I'm sorry. I don't remember. I couldn't tell you.

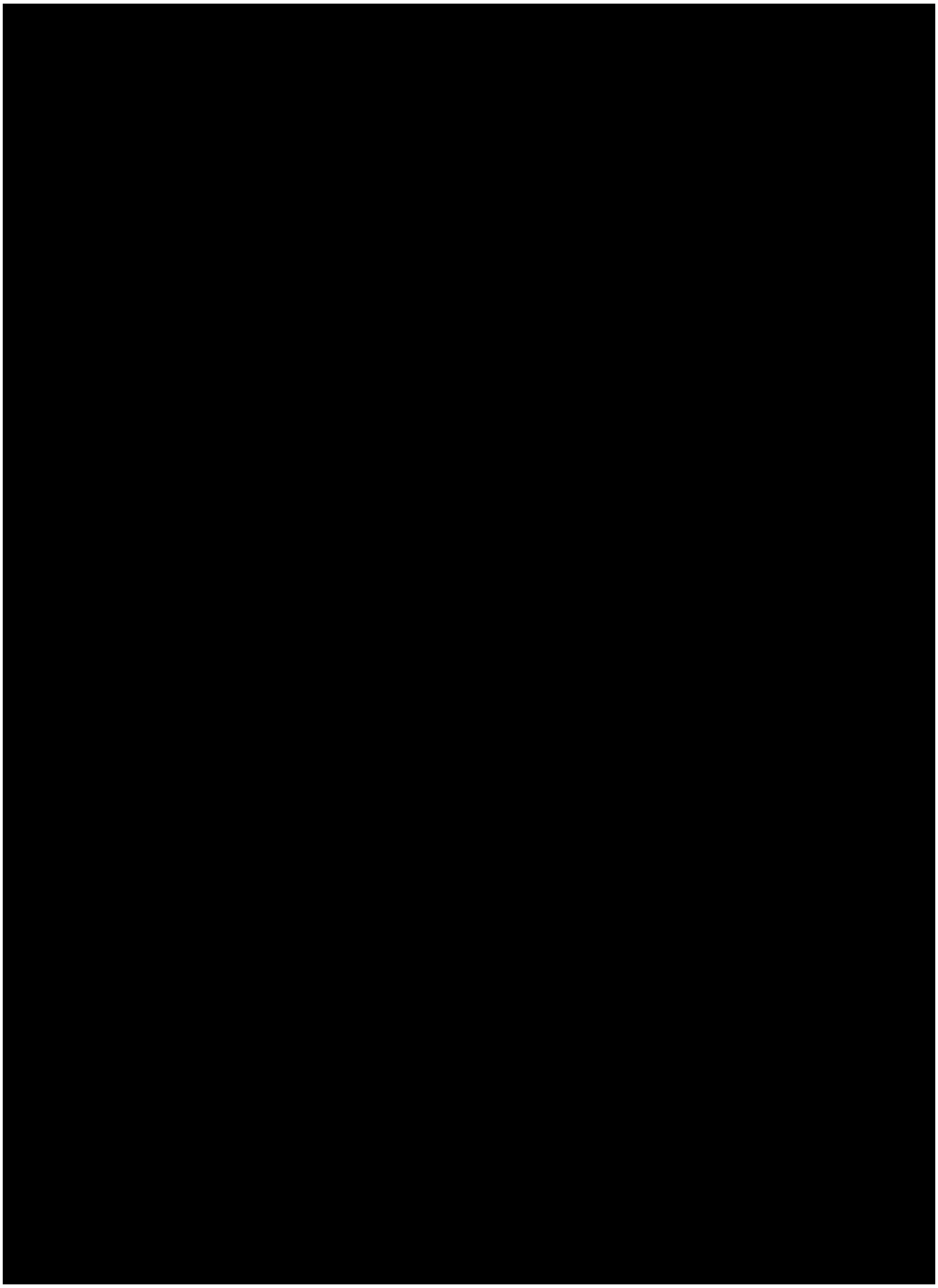
Q Okay. But whether you remember the number or not, is there an SOP that deals with this narrow issue, if you find an out-of-spec tablet in the current batch, you must look for history or pattern of prior occurrences of out-of-spec tablets?

A There is not an SOP that is specifically talking about what you do if you find a specific attribute failure. There is an investigation procedure that tells you how you go about conducting an investigation. That's the procedure you would need to look at.

Q Do you feel, whether or not the FDA said something about it, that it was inappropriate for you as quality assurance director not to look for whether there was prior out-of-spec Digitek tablets before November 30, 2007, having found these 20?

MR. MORIARTY: Objection; form.

THE WITNESS: And, again, I didn't say we did not. I said there were



Do you know that the FDA investigators were questioning the judgment of some of Actavis' investigations and their outcomes?

A Yes, I was aware of that.

releases?

MR. MORIARTY: Objection.

Go ahead.

BY MR. PETTIT:

Q Do you remember in January, February, March, April 2008 whether you were ever told that the FDA was focusing on especially some of the batch releases?

A I know they were looking at investigations and the investigation process. But focusing on the batch releases, I do not recall that being a conversation.

Q Wouldn't the outcome of an investigation be whether or not there was a batch release?

A Not necessarily. Investigations could be tied to other parts of the operation.

Q But in any event, the FDA -- it's your testimony that you are aware, this e-mail aside, that the FDA was focusing on batch releases in that time period; correct?

A No. I said I was under the understanding that they were focusing on investigations. I didn't know about the specific piece of batch releases.

Q Did you know that Divya Patel, the CEO or president, was telling another high-ranking official in the company a comment about Dan Bitler? Did you know you were being discussed at that high level of the company?

A I know nothing about this information, no.

Q Is this the first time you knew Divya Patel was talking about you in April 2008?

A From my own firsthand experience, this would be the first time that I know, yes.

Q So this e-mail surprises you?

A No.

Q So -- well, let me ask you a specific question about this sentence. Is it

true that you as the quality assurance individual on-site who has this responsibility, talking about the previous phrase, is no longer releasing batches, is that true at that time, April 2008?

A I can't refer back to the exact date, but the statement that I was not releasing batches was -- is a true statement, yes. Phyllis did discuss that with me.

Q Okay. And the parentheses says Phyllis, which is Phyllis Lambridis, immediately put -- I'm paraphrasing -- put Dan Bitler's ability to release batches on hold. So that's what you're talking about?

A Correct.

Q And when did Phyllis have that conversation with you, Phyllis Lambridis?

A I'm sorry. I can't recall. I can't recall the dates.

Q Okay. Was it -- so this e-mail is a couple weeks before the recall of Digitek. Can you answer my question in that fashion, how many weeks or months before the recall she was taking you off -- taking away your ability

to release batches?

A I, again, don't have the dates. I mean, looking at this document, I would -- I don't want to assume. I don't know what the dates were.

Q Since the president/CEO, Mr. Patel, was talking in an e-mail to another high-ranking official about Dan Bitler being -- having his ability to release batches removed by the vice president, would that mean to you that the writing was on the wall in terms of your going to be let go soon?

MR. MORIARTY: Objection.

THE WITNESS: I can't answer the intent or what their thoughts were at this particular point in time.

BY MR. PETTIT:

Q Does the focus of your ability to release batches being taken away, does that focus in this e-mail being talked about by the president of the company, does that show you the importance to the company of your decision making about your decisions to release batches?

MR. MORIARTY: Objection.

THE WITNESS: I'm sorry. I don't quite understand that question.

BY MR. PETTIT:

Q Have you ever prior to five minutes ago known that the highest levels of this company were talking about your ability and whether you should have the ability and whether you had the ability taken away to release batches?

A No, I was not aware.

Q Based on your four or five years at Actavis, does it seem an unusual event that the president of the company would be involved in discussing whether or not your ability to release batches was something important enough to tell Siggi Olafsson about?

MR. MORIARTY: Objection.

THE WITNESS: I can't say what's usual or unusual. I'm sorry.

MR. PETTIT: I think this is not a preexisting marked exhibit, but I'm not a hundred percent sure. So I'm going to mark this as 132.

(Plaintiff's Exhibit No. 132 was marked for identification.)

MR. PETTIT: For the record, this is a document which I will identify on the front page as being on the letterhead of Actavis dated June 11, 2008. And it's directed to Douglas Ellsworth, District Director New Jersey District for the FDA. And it's regarding an FDA 483, which was issued to Actavis on May 20, 2008.

Go off the record for one second.

THE VIDEOGRAPHER: Off tape, 2:27.

(Discussion off the record.)

THE VIDEOGRAPHER: Back on tape, 2:28.

BY MR. PETTIT:

Q Sir, can you look at Page 8 of 19?

A Okay.

Q First of all, have you seen this response letter before just now?

A No.

Q Have you seen response letters from Actavis from some other investigation so you at least know what the concept is, they write a response letter after getting a 483?

A I understand the concept, yes.

Q And on Page 8 of 19, they're talking about Observation 4, which would mean Observation 4 of the 483, which was a form from the FDA in May 2008. And it says: "Determinations of conformance to appropriate written specifications for acceptance are deficient for in-process materials."

And without reference to the particular sentence, what are in-process materials? What's that word mean?

A In-process materials would or could be anything from manipulations of the starting raw materials anywhere through to the point at which you're packaging the final dosage form. You've got different parts of the operation where you will complete a phase, may capture and store material for a period of time before going to the next phase of the manufacturing or packaging operations. So these are

in-process materials because they're at different steps in the process.

Q Again, this is part of a multipage letter from October advice to the FDA dealing with the FDA's Observation 4. And it's saying specifically -- now, I'm going to paraphrase and read the sentence, but this is dealing with batches other than the batch we've been talking about. So this is other than the 70924 double-thick batch; correct? These are all different batch numbers; correct? And there's three of them: 70148A, 70207A, 70707A. Do you see those numbers?

A Yes.

Q Now I'm going to read the sentence: Although three out-of-specification results were obtained for blend uniformity at the -- and there's a redaction -- sample location for digoxin tablets .125 in 70148A, 70207A -- and I'm skipping some letters here but it's on the screen -- and 70770A on February 20, 2007, March 14, 2007, and September 29, 2007, no manufacturing investigations were conducted.

Now, you were still quality

to some other conclusion, I wouldn't have been aware of those out-of-specification results. So what I'm saying, I don't know if there was or there was not.

BY MR. PETTIT:

Q Okay. And that's the same for 70207A in March '07 and 70770A in September '07; correct?

A Correct.

Q So if there were -- what does the phrase "manufacturing investigations" mean? In terms of finding an out-of-spec result for Digitek, what would "manufacturing investigation" mean?

MR. MORIARTY: Objection. Go ahead.

THE WITNESS: Every time you have an out-of-specification result does not automatically mean you have a manufacturing investigation to go with that. If you have an out-of-specification result in the laboratory, the laboratory has written procedures, SOPs, on how to go about

investigating that initial result. And if upon that investigation a cause is determined and it's found to be laboratory-related, there will not be any manufacturing investigation to go with that result. So just because you have an OOS doesn't mean you have automatically a manufacturing investigation also.

BY MR. PETTIT:

Q Well, I'm sure it wasn't automatic because it wasn't conducted. So let me ask you: Is there a policy that determines that if there's a lab result showing out-of-spec Digitek, that there should or should not be a manufacturing investigation conducted?

A There would be --

MR. MORIARTY: Objection.

THE WITNESS: Sorry.

MR. MORIARTY: Go ahead.

THE WITNESS: There would be an investigation SOP in the laboratory that would discuss steps to be taken during the investigation process.

BY MR. PETTIT:

Q And could there be a decision to have a manufacturing investigation? Is that one possibility?

A That is correct.

Q And the laboratories are under quality control? Is that the setup, the organizational setup?

A That's correct.

Q And do you have any involvement with quality control laboratory testing?

A You have to define "involvement." I'm not sure what you're --

Q Involvement to the level where they would discuss with you whether there should be an investigation because there was out-of-spec Digitek found.

A Not necessarily. I can't say that they would not call and say, "This is what we're looking at." But if they follow procedure, there would not necessarily be any need for a manufacturing investigation.

Q Would -- in 2007, would Richard Dowling have been involved in a discussion

A Correct.

Q There's a column here, the heading is Reviewer and it says R. Haluska. Do you know who that is?

A It's, I believe, a member of Quantic.

Q What is that?

A An outside consulting firm.

Q What did they do in the spring of 2007?

A They were brought in to review a sample of batch records, the 302 sample.

Q What is that?

A It's the number of batches that were taken from a list of batches produced that they were going to sample and review for our organization as part of what was called QSIP.

Q And was QSIP for this particular issue set up after an FDA inspection?

A QSIP was set up after an FDA inspection, that is correct.

Q And it says date question was issued, May 22, '07. Is that the issue of investigating out-of-spec Digitek?

A No.
Q Do you know what that means?
A That's the date that Mr. Haluska had a question that he wanted to have answered about this particular batch record and provided that question to the appropriate department to have sent somebody over to sit down with them to talk about whatever question he had.
Q Did you have any involvement with this outside group for this project, this task?
A Yes.
Q Did you ascertain that there was an out-of-spec Digitek tablet that was out of spec for weight?
A I --
MR. MORIARTY: Objection.
Go ahead.
THE WITNESS: I couldn't say that I was the one who responded to that particular question on this particular batch. I don't recall.

that arose during that review process by this individual consultant.

Q And do you know what the conclusion was?

A I can't say.

Q I'm showing you what was previously marked at an earlier deposition Exhibit 91. And it is a photocopy of an EIR, an Establishment Inspection Report, regarding Actavis Totowa where the start date is March 18, 2008, and the end date is May 20, 2008. Have you ever seen this document before?

A No, sir.

Q Have you ever heard of an EIR?

A Yes.

Q And what is your understanding of what an FDA Establishment Inspection Report is when it's sent to a company?

A At the conclusion of the inspection, they compile all of their information and send it out to the organization as the overview of that inspection that took place.

Q Turning to the second page, Page 2

of 95, when the FDA is talking about the inspection, they say the inspection was limited to coverage of the quality system. And then the sentence goes on. Please read the whole sentence if you need to. But was it your understanding that FDA inspection was limited to coverage of the quality system?

A That wasn't my understanding, no.

Q And was it your understanding that an issue for the FDA at that time was the batch that we've been talking about for hours, which is the Digitek Batch 70924A, which they call 70924A2 here? Did you know that that was a focus of the inspection by the FDA?

A Yes.

Q Did you know that the FDA was critical of the failure of the quality unit to reject products not meeting specifications?

A No.

Q No one ever told you that?

A I never saw the 438 or EIR. No, I wasn't aware.

Q But putting aside whether you saw the documents, nobody told the quality

assurance director that the FDA was critical of the failure of the quality unit to reject products not meeting specifications?

MR. MORIARTY: Objection. This is May 20. He probably wasn't even there then.

MR. PETTIT: Please, sir, just object.

BY MR. PETTIT:

Q The question was: No one ever told you that?

MR. MORIARTY: Objection.

THE WITNESS: No, because you're talking about in this case the quality unit. That's not quality assurance by itself. It's the quality unit.

BY MR. PETTIT:

Q What's the quality unit?

A That includes quality control, laboratories. When you say not meeting specifications, it could be laboratory-related. It could be -- validation's part of the quality unit. It

could be validation-related. It could be manufacturing. The quality unit encompasses all quality systems and all quality members of the organization. It's not just quality assurance.

Q But it sure could be focused on the release of Digitek tablets Lot 70924A2 following a visual inspection, could it not?

MR. MORIARTY: Objection.

THE WITNESS: That was a single item that they were looking at was that investigation.

BY MR. PETTIT:

Q So out of all of the many, many products Actavis made, they made a point of having an inspection that was focused on something which they spelled out, and they actually spelled out the name of the drug, digoxin tablets, which is Digitek, the lot number, the dosage, the fact that there was a visual inspection. Did anyone ever tell you that the FDA in this inspection was focusing on your release of Digitek 70924A2 after a visual inspection?

MR. MORIARTY: Objection.

THE WITNESS: Not worded that way, no. That's not correct. The FDA did not come in to focus on this batch. They came in for an inspection. This was an item that was discovered and discussed as part of that inspection process was this particular batch. They didn't come in for this batch.

BY MR. PETTIT:

Q I didn't say in my question this was the only thing they did. This is a 95-page report. I'm saying: Did anyone tell you that they were so interested that they spelled out in the EIR the product, which is Digitek or digoxin tablets, the dosage, the lot number, and the fact that it was released following a visual inspection? Did anyone tell you that that, in fact, was something that they were looking at with that specificity?

MR. MORIARTY: Objection.

THE WITNESS: No one ever told me about the EIR because I was no longer with the organization when they received

Quality Assurance group, the lack of oversight of decision making and the failure to respond to product quality issues were all observed as continuing problems during the current inspection despite the improvements in the laboratory."

Were you ever told that the FDA prior to your being let go was critical of the lack of oversight of decision making in quality assurance?

MR. MORIARTY: Objection.

Go ahead.

THE WITNESS: No.

BY MR. PETTIT:

Q Do you believe that there was a lack of oversight of decision making in quality assurance?

A No, I do not.

Q Do you believe that there were, quote, limited resources of the quality assurance group, unquote?

A I don't know why the inspectors thought the resources were limited. I'm not really sure.

A Just felt that we could continue to enhance and improve the operation with more resources.

Q If you turn to Page 12, this is concerning Misbah Sherwani, who we talked about earlier, senior manager quality assurance investigation group; correct? I mean correct, is that her title?

A Yeah, I think it was. I think that's correct at the time. I don't recall but that sounds about right.

Q Apparently she explained to the FDA the efforts to correct the backlog of incomplete QA investigations and stated that she hoped to hire additional resources.

Did you know that Misbah Sherwani had explained to the FDA there had been efforts by the company made to correct the backlog of incomplete QA investigations?

A No, sir.

Q Do you agree that there was a backlog of incomplete QA investigations?

A No.

Q Do you think Misbah Sherwani was

wrong in reporting that to the FDA?

MR. MORIARTY: Objection.

THE WITNESS: I can't speak to why Misbah said what she said.

BY MR. PETTIT:

Q No, I'm not asking for her motivation. I'm asking if factually you contend she was wrong.

A But you're asking for what I feel is a backlog versus what she feels is a backlog, so it still comes down to something that is opinion, not fact. And I don't know what her opinion was or why.

Q Wouldn't a backlog be something -- an incomplete QA investigation; in other words, QA investigations weren't kept current?

A They were kept current. But, again, an investigation takes time. An investigation to be done correctly takes time.

Q Well, she hoped to hire additional resources to correct that problem; correct? Do you agree with that?

A No. You have to ask her why she said what she said. I don't know.

Q So you don't know if she hoped to correct the problem by giving you more people in quality assurance?

A This would have been her people. She was in charge of investigations.

Q Okay. So that would have no impact on the quality assurance, the fact that she would have more people in quality assurance?

A She didn't report in to quality assurance. She didn't report in to me. If you read below, she reported to Phyllis.

Q Okay. So quality assurance in some other sliver of it was trying to get more people to bring their QA investigations more current; would you at least agree with that?

A Based on what is written here, that's what it appears to say.

Q And you just don't believe there was a backlog; is that your testimony?

A In my opinion, I don't know what she's considering to be a backlog or what she is not considering to be a backlog.

MR. PETTIT: I have a minute left on the tape, so I better stop.

the quality assurance group looking for whether or not there were any more out-of-spec Digitek tablets, that that part was inconclusive?

MR. MORIARTY: Objection.

THE WITNESS: Don't know anything about that.

BY MR. PETTIT:

Q Did anyone tell you that the FDA was critical that you did not extend the investigation to all other lots or strengths of digoxin tablets?

A No.

Q And "all" would certainly refer to prior lots and strengths of Digitek; that's your understanding of what "all" would mean, right, all other lots?

A I didn't write this, but it would appear to be the case.

Q Turn to Page 20. The FDA is saying quality assurance investigations were not documented and/or not completed, reviewed, or approved at the time of the findings.

Did anyone ever tell you that the

FDA was critical about quality assurance investigations in that way?

MR. MORIARTY: Objection.

THE WITNESS: No.

BY MR. PETTIT:

Q "Additionally, decisions for finished product release were not supported by scientific rationale" -- well, I'll stop there and I'll continue the sentence in a minute.

Did anyone ever tell you that the FDA was critical that decisions for finished product release were not supported by scientific rationale?

MR. MORIARTY: Objection.

THE WITNESS: No.

BY MR. PETTIT:

Q The sentence goes on: "And investigations of deviations were not reviewed by multiple personnel in the Quality Unit for concurrence."

Did anyone ever tell you that the FDA was critical that quality assurance investigations of deviations were not reviewed by multiple personnel in the quality unit for

concurrence?

MR. MORIARTY: Objection.

THE WITNESS: At this point in time when this occurred, no.

BY MR. PETTIT:

Q Any other time?

A When you told me -- when we discussed this earlier today, the fact that the question had come up when I was with these gentlemen last night at Phyllis' depo, that's the first I'd heard of it.

Q Did anyone ever tell you the FDA was critical of the paper-based systems for documenting laboratory investigations, manufacturing investigations, and quality investigations in that they were not managed, trended, or correlated to determine the comprehensive impact on marketed product?

MR. MORIARTY: Objection.

BY MR. PETTIT:

Q Did anyone ever tell you that?

A Wait a minute. Where is this at?

Q It's the same paragraph.

A Oh, I'm sorry.

No. And there's no requirement that you can't use paper-based systems.

Q Well, it looks like the criticism is not just that they were paper-based, but they were not managed, they were not trended, and they were not correlated in order to determine the comprehensive impact on marketed product, in other words, how that was used.

A I understand that part of the sentence and the answer to that was no. I'm just highlighting the fact that there is no requirement you cannot use a paper-based system.

Q No, I wasn't suggesting that.

Did anyone ever tell that you the FDA was critical of the fact that written procedures were not followed? And I'll finish the sentence in a second.

A I'm sorry. Was that --

Q Yes. Did anyone ever ask you that?

A I thought you were going to continue. Can you ask the question again, please?

Q I just wanted to take it a half a

sentence at a time.

Did anyone ever tell you that the FDA was critical that written procedures were not followed?

A No, I did not know that was an issue with that inspection.

Q Did anyone ever tell you that the FDA was critical that staffing was insufficient to support the large number of quality investigations required based on laboratory findings?

A I know early in the inspection one of FDA's concerns that they saw was the size of the quality unit. But as far as this specific item here, investigations required based on laboratory findings, no, that I was not aware of.

Q Could you turn to the next page, Page 21. This is regarding Observation 2 that the FDA made in the 483, but I just want to talk about the last sentence in the paragraph. There was no documented evaluation of the approximately blank number of -- well, redacted number of lots that remained on the

market at the time of inspection. And, again, they're dealing with the Digitek batch we were talking about earlier.

Did anyone ever tell you that the FDA was critical that there was no documented evaluation of the other lots of Digitek besides 70924A1 that were on the market at that time?

A I don't know that I would classify it as critical as you're saying. I know that that was part of their discussion, but that's the only thing that I was made aware of.

Q You think that they're praising you for not having documented evaluation?

A I think they're providing their opinion of what they saw.

Q But it's a critical sentence, is it not?

MR. MORIARTY: Objection.

THE WITNESS: It's a sentence.

BY MR. PETTIT:

Q That's just a sentence? The FDA's saying that in an observation in a 483 -- would you agree that an observation in a 483

is something they want the company to look at and address?

A That they want us to look at and address? Yes.

Q Yes. And so they're not praising the fact that you have no documentation, are they? They're telling you that's a problem and you should look at it and address it; do you agree with that?

A I agree with the fact they would want us to look at it and address it, yes.

Q So the only part you disagree with is that lack of documentation is a problem; is that your testimony?

MR. MORIARTY: Objection.

THE WITNESS: No. My objection was your use of the word "critical." You took one sentence out of the whole thing and said this is critical. I agree with you it is something they would want us to look at and address.

BY MR. PETTIT:

Q Can you turn to the next page, please, 22. They're still talking about that

Q Okay. I'm going to show you a document that's previously been marked as Exhibit No. 49. I think you mentioned earlier the term "good manufacturing practices."

A Yes.

Q What is that term?

A Current good manufacturing practices, GMPs, or CGMPs.

Q And based upon your long experience in quality involving pharmaceuticals, what's the purpose of CGMPs?

A Current good manufacturing practices are basically to set up standardized procedures that will be followed time after time in the running of your operation.

Q Okay. So one of the things that's being done by having this set of practices called good manufacturing practices is to standardize quality assurance and quality control procedures, and manufacturing procedures across industry?

A That would be correct.

Q Is it also important from a safety standpoint?

A Referring to the safety of the product or --
Q Yes.
A -- safety of the employees?
Q Both.
A It could be for either case, yes.
Q Okay. So there is a safety component to the good manufacturing practices and the enforcement of those practices?
A Yes.
Q I think you were asked earlier by Mr. Pettit whether these were minimum standards, and I can't remember exactly what your answer was with respect to that. But if you would take a look at the document that's in front of you that was marked Exhibit 49, do you see that in the first paragraph under Part 210, Section 210.1 where it says "Status of current good manufacturing practice regulations," do you see where it says that this chapter contains the minimum current good manufacturing practice for methods to be used in, and the facilities or controls to be used for, the manufacture, processing, packing or

holding of a drug to assure that such drug meets the requirements of the act as to safety and has the identity and strength and meets the quality and purity characteristics that it purports or is represented to possess?

A I see that.

Q Okay. So does it say essentially in the first paragraph of the regulations that they're minimum standards?

A It does say that, yes.

Q Okay. And do you see in the second paragraph that it actually says that a failure to comply with these regulations renders the product adulterated?

A Right.

Q Okay. Now, were these the regulations that you were asked to study and that you had a refresher course on from time to time while you worked for Actavis?

A These were the regulations that we would reference when looking at what the regulations required, yes.

Q And was there -- were there tests administered from time to time at Actavis to

determine whether people were familiar with those regulations?

A Not that I'm aware of.

Q Do you know whether any tests were administered after the FDA inspection in 2008 and before you left the company?

A Not that I'm aware of.

Q I'm going to show you next -- this may have been marked as a prior exhibit, but I don't have it on here. I'm just going to show you pending figuring out whether we have a prior exhibit or we need a new exhibit some additional regulations that I believe specifically apply to quality.

Are you familiar with these regulations that begin at Section 211.22 of the 21 CFR?

A Yes, sir.

Q Okay. And tell me what these regulations apply to generally.

A Well, you're talking about subpart B, which refers to organization and personnel.

Q So this would essentially specify the responsibilities of personnel within

quality control organizations; correct?

A The first section would, yes.

Q Okay. Do you see where it says there that: "There shall be a quality control unit that shall have the responsibility and authority to approve or reject all components, drug product containers, closures, in-process materials, packaging material, labeling, and drug products, and the authority to review production records to assure that no errors have occurred or, if errors have occurred, that they have been fully investigated"?

Do you see where they like to write long sentences?

A Yeah.

Q Do you understand that paragraph to require that a drug company that produces prescription drugs has to have a quality control unit that has both the responsibility to act and the authority to act?

A Yes.

Q And they should have the authority and responsibility not only to approve but to reject materials; do you see that in the

regulations?

A Yes.

Q Do you see also that over here in the second column, I think it's under Section 211.25, (c) says: "There shall be an adequate number of qualified personnel to perform and supervise the manufacture, processing, packing, or holding of each drug product"? Is that what it says?

A Yes.

Q So they're telling you you have to have enough people to do the job; correct?

A You need that back?

Q Yes. But before I mark it, maybe an answer to the question.

You need enough people to do the job?

A They're saying you need to have adequate staffing, yes.

Q Okay. And I think you mentioned earlier that you were familiar with the fact during the 2008 inspection that the company -- that FDA had concern about the size of the quality unit being too small?

A I know that was a discussion item, yes.
Q Right. And you've actually had that concern also, haven't you?
A From time to time, of course. Everyone wants to get more head count.
Q Well, I mean, there were times that you were busier than a one-armed paperhanger with a case of the hives; right?
A I've been busy at times, yes.

MR. BLIZZARD: Let me mark as Exhibit 134 a copy of the regulations relating to the quality control unit that we just talked about.

And now I'm going to mark as the next exhibit Exhibit 135.

(Plaintiff's Exhibit No. 134 was marked for identification.)

(Plaintiff's Exhibit No. 135 was marked for identification.)

BY MR. BLIZZARD:
Q This was an e-mail you wrote in October of 2007; is that right?
A According to the header on this,

yes, that is correct.

Q I've got a couple of questions about this, but I want you to take a look at it long enough to tell me whether you remember writing this e-mail.

A Yes, I believe this is correct.

Q Looks like from reading the e-mail that you wrote this on a Sunday?

A Yes, sir.

Q It says that you had actually -- this is paraphrasing -- caught a break and didn't have a lot of requests, people were helping you out while the FDA was at the plant doing an inspection, but then everything broke loose after the FDA left. And it says I think everybody and their brother was bombarding you with requests; is that right?

A That's what it says.

Q And then you in the third bullet point, it says: Mike and I completed at least four, maybe five investigations this week.

Is that what it said?

A That's what it says.

Q What was a typical number of

investigations that your -- you and Mike had to complete in a week?

A I honestly don't recall. It's very investigation-specific as to how long it takes. I really don't recall what that would be.

Q And Mike is Mike Ponzo?

A That would be Mike Ponzo, yes.

Q And were he and you the ones that were principally involved in doing these investigations at this period of time?

A At this point in time. This is prior to Misbah coming down from Elizabeth. So, yes, this would be Mike and I.

Q So the two of you, Mike Ponzo and yourself, had the responsibility from October 2007 and in that time frame until when Misbah came down?

A I don't recall if she came down before the start of the year or after the start, but it was somewhere end of December and January time period. I don't recall the exact dates.

Q Okay. So you added a third person

at that point?

A She was not full time. She was working in Elizabeth and as an investigations group manager. So they were using her to come up here for a couple days to assist us and then a couple days in Elizabeth to work with them.

Q Okay. And also at this time it looks like you were interviewing other candidates to work in the both QA packaging and QA manufacturing; correct?

A We were interviewing for the packaging position. We had not begun yet. We only had put a proposal together I think at this point is what we're saying to HR for the manufacturing position.

Q Did these guys get hired?

A You know, I don't believe so. I don't think they did, no.

Q Okay. So --

A There's one person that got hired in packaging. I believe she was before this. So I don't think so.

Q Okay. So at least as of October 7

A Yes.

Q It says: "Actavis Totowa's laboratory and manufacturing facilities were inspected by the FDA in August 2006 and received 15 observations in the form of an FDA 483. We were provided documentation showing all corrective actions have been completed."

Do you see where it says that?

A Yes.

Q Now, you've talked about that inspection by FDA in 2006 earlier today; correct?

A We had a conversation, I believe, yes.

Q Okay. So there was an inspection in the summer of 2006 by FDA that you're familiar with; right?

A Yes, sir.

Q And then following that inspection, FDA issued a Form 483, which makes observations that they want you to take a look at and reply to and, if necessary, correct; is that right?

A That would be correct.

A Somebody's compilation of status it appears for what has taken place in response to observations.

Q So if you look at the first page, does it say at the top "August 2006 GMP Inspection Totowa?"

A Yes.

Q And was that the same inspection we just referred to from that Mylan audit?

A I believe so, yes.

Q And the first observation from that inspection was failure of the quality unit to fulfill its responsibilities, failure to fully investigate errors; all lab data not included with batch records; manufacturing deviations not always documented? That was the observation from the FDA inspection; correct?

A I am assuming that what's in here is correct. I don't know.

Q I'm going to hand you what is previously marked as Exhibit No. 68, Mr. Bitler, if you'll just take a look just so we can be sure of this. Does Observation No. 1 from this document that we're looking at

does it say essentially the same thing, quality unit failed to assure that laboratory notebooks included all data, et cetera?

A It does seem to paraphrase without any of the examples.

Q Okay. And now if you look at this spreadsheet, there's a section that paraphrases the actual observation by the -- or column that paraphrases the observation by the FDA. There's then a listing of the Totowa action items. And then there's another column for documentation needed; correct?

A Yes.

Q And then there's a column that says date verified correction; correct?

A Yes.

Q And then there's a column for responsible person and comments. Do you see that?

A Yes.

Q Okay. So Observation No. 1, failure of quality unit to fulfill its responsibilities, yada, yada, yada, you look under over here under "Date verified

correction," it says "not corrected"; correct?

MR. MORIARTY: Objection.

Go ahead.

THE WITNESS: Well, that's what is on this document.

BY MR. BLIZZARD:

Q Right.

A True.

Q And they actually give a date of July 19th of '07; correct?

A That's what's on this document, yes.

Q So if we assume that Mylan was given documentation in December of '06 that all these observations were corrected, that documentation was false, wasn't it?

MR. MORIARTY: Objection.

THE WITNESS: I don't know what Mylan received. I can't speak to that.

BY MR. BLIZZARD:

Q Okay. Well, certainly, at least according to this document, Observation No. 1 was not corrected, was it, as of July 19th of '07?

A Again, I don't know who wrote this.

remainder of the pages, are most of them showing either corrected or partially corrected?

A It appears so, yes.

Q Okay. Now, do you know whether this information was ever shared with Mylan?

A I don't even know who put this information together.

Q Okay. So maybe that's -- I need to make that clear. Did anybody ever sit down that you can recall and tell you, Mr. Bitler, we haven't completed, we haven't corrected Item No. 1, we need to get busy with that from August 2006 audit?

A We had a plan going forward of correcting the things that were identified in that inspection. It was called QSIP.

Q You mentioned that earlier. What is the actual acronym there? How is the spelling of that acronym?

A Q-S-I-P.

Q So that's the Quality Systems Improvement Plan?

A Correct.

Q And who was in charge of QSIP?
A I believe -- I'm not a hundred percent sure. It was Nasrat's idea to use the QSIP idea, but I don't recall who was the lead on managing that project.
Q When did Nasrat Hakim leave the company?
A I can't recall. I'm not sure.
Q Was there a period of time where that position was vacant?
A Yes.
Q Do you know how long that period was?
A I know Scott came January-February of 2007. No. Wait. I'm thinking of Phyllis. I'm sorry. I got the wrong people there. Phyllis came in September of '07. And I don't recall when during '07 earlier Nasrat left. I'm not sure what the time period was.
Q So the succession of Scott's boss would have been Nasrat and then Phyllis?
A Correct.
Q And there was some gap between Nasrat leaving and Phyllis starting, but

digoxin tablets?

A You'd have to pull the batch cards to get the numbers. It was only -- it was a limited number that were used.

Q Were those Stokes units also used to manufacture other medications made and sold by Actavis?

A They could be, yes.

Q Okay. Do you know what rooms were used to manufacture digoxin over at the Little Falls facility?

A They were the same two rooms that were used all the time. And I'm sorry, I can't remember the numbers. But they were the same rooms that were used constantly.

Q So there were two rooms and they were used repeatedly --

A Yes.

Q -- for digoxin?

A Correct.

Q Now, over at Riverview, how many different rooms were used?

A I believe they were working on only two at the time, I believe. I think there was

A No, sir.
Q Were you ever made aware of metal shavings being found?
MR. MORIARTY: Objection. You mean in Digitek?
BY MR. BLIZZARD:
Q I'm asking whether you know of any metal shavings being found in pills that are made.
MR. MORIARTY: Objection.
You can answer as to Digitek.
THE WITNESS: Not that I'm aware of. I'd have to go back and review the documentation.
BY MR. BLIZZARD:
Q Okay. What does it mean when it says "punches are not measured after each batch"?
A Honestly, I don't know what she's requesting there. That's not something industry practice that I'm aware of.
Q If you go over to the next page, under the heading of Comments, do you see where it says: Don't check or replace worn

equipment; no preventive maintenance for tableting punches?

Do you see that?

A I see the statement, yes.

Q And then right underneath that it says: Metal shavings found on tablets.

Do you see that?

A I see it's written in here, yes.

Q Screws found with tablets?

A I see that.

Q Are you familiar with screws being found with tablets?

A Yes.

MR. MORIARTY: Objection.

Go ahead.

THE WITNESS: Yes.

BY MR. BLIZZARD:

Q When did you find out that -- what screws were found with tablets?

MR. MORIARTY: Objection.

You can answer -- go ahead and answer. Don't mention other products.

THE WITNESS: When you say "what screws," what -- can you rephrase

or redefine what you're trying to get?
BY MR. BLIZZARD:
Q I'm just trying -- I guess I'm kind of surprised that pills are being produced with screws. And so I'm wondering what it means where it says under the heading of no preventive maintenance for tableting punches, it says screws found with tablets.
A Right. And the reason being is that equipment's held together with screws and that occasionally a screw will back out and occasionally you'll find it mixed with the tablets. And as part of that investigation process, that's taken care of. And that's why you have metal detectors.
Q Okay. What's the next bullet point say?
A Digoxin, a toxic product with double, triple, and thin tablets; lots were not rejected; partial lot released -- partial lot releases.
Q Okay.
A Okay.
Q Do you have any experience with

A No, sir.

MR. BLIZZARD: We may have to substitute the first page of this exhibit later because I think there's some handwritten notes on here that are added notes.

(Plaintiff's Exhibit No. 147 was marked for identification.)

BY MR. BLIZZARD:

Q Let me show you what's marked as Exhibit No. 147. Do you know Jacob Haroon?

A I know who he is, yes.

Q If you look at -- the FDA inspection was concluded I think, according to the records, on May 20th of 2008. Does that sound about right to you?

A I believe that's about right, yes.

Q And it shows in this exhibit that Phyllis Lambridis sent this e-mail to Jacob Haroon on Friday, May 23rd, 2008, Subject: For your reading pleasure; correct? Is that what it says?

A Yes, it does.

Q And it says: You can share with

your group but please do not give out copies. And then it says: Enjoy, exclamation point. Correct?

MR. MORIARTY: Objection. Just for the record, the copies that Mr. Bitler and I have don't look like this.

MR. BLIZZARD: Oh, okay.

MR. MORIARTY: There's some handwriting that obscures the words do not give out copies.

MR. BLIZZARD: Okay. And that's why I said we're going to have to substitute. I do have -- the one I've highlighted here, which is on the screen, doesn't have those handwritten comments on it, so that's why I know that those are added. And so we will substitute the original first page. And I'll let you look at this.

MR. MORIARTY: Why don't you just put that one in as the exhibit.

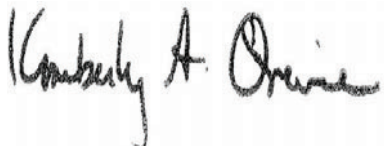
MR. BLIZZARD: We can do that. It's just highlighted. We'll just delete

A Correct.
Q And it says: "This is all rather sad. Looks like some very basic GMP knowledge was lacking."
Is that what it says?
A That's what it says.
Q Do you agree with that?
A No, sir.
MR. BLIZZARD: I don't have any additional questions of you at this time.
MR. PETTIT: I might literally have one. Let me just ask Ed a question.
THE VIDEOGRAPHER: Off the record, 5:29.
(Discussion off the record.)
THE VIDEOGRAPHER: Back on the record, 5:34.
BY MR. BLIZZARD:
Q Mr. Bitler, were you the one who was handling Investigation 08-060 on the overweight pills for the quality assurance department or was there someone else?
A Can I --
Q Yes.

CERTIFICATE

I HEREBY CERTIFY that the witness was duly sworn by me and that the deposition is a true record of the testimony given by the witness.

It was requested before completion of the deposition that the witness, DANIEL W. BITLER, have the opportunity to read and sign the deposition transcript.



KIMBERLY A. OVERWISE
Certified Realtime Reporter
Notary Public
Dated: February 6, 2009

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INSTRUCTIONS TO WITNESS

Please read your deposition over carefully and make any necessary corrections. You should state the reason in the appropriate space on the errata sheet for any corrections that are made.

After doing so, please sign the errata sheet and date it.

You are signing same subject to the changes you have noted on the errata sheet, which will be attached to your deposition.

It is imperative that you return the original errata sheet to the deposing attorney within thirty (30) days of receipt of the deposition transcript by you. If you fail to do so, the deposition transcript may be deemed to be accurate and may be used in court.

ACKNOWLEDGMENT OF DEPONENT

I, DANIEL W. BITLER, do hereby certify that I have read the foregoing pages, 1-336, and that the same is a correct transcription of the answers given by me to the questions therein propounded, except for the corrections or changes in form or substance, if any, noted in the attached Errata Sheet.

_____ _____

DANIEL W. BITLER DATE

Subscribed and sworn
to before me this
____ day of _____, 2009.

My commission expires:_____

_____
Notary Public